

REMARKS

This paper is submitted in response to the pending Office Action mailed on October 14, 2005. Because this response is submitted with a certificate of mailing in compliance with 37 C.F.R. §1.8 on or before the shortened period for reply set to expire on **January 14, 2006**, this amendment is timely filed.

I. STATUS OF THE CLAIMS

Claims 1 to 65 were originally filed and pending in this application.¹ By this response, claims 33 to 36, 39 to 42, 44, 46 to 49, 51, 53, 54, 56 to 60 and 62 to 65 have been amended to ensure proper dependency, claims 7 and 25 have been canceled and no new claims have been added. While Applicant believes that no other extension or claim fees are due in connection with this application, Applicant respectfully requests that **Deposit Account No. 02-1818** be charged for any fees deemed owed during the pendency of this application, excluding the issue fee.

II. CLAIMS REJECTIONS

The Office Action provisionally rejects claims 1, 5, 8 and 28 under 35 U.S.C. §101 as being potentially double patented over claims 24, 25, 27 and 28 of co-pending U.S. patent application serial No. 10/624,150. The Office Action rejects claim 1 to 61, and presumably renumbers claims 1 to 65, under 35 U.S.C. §102(f) as having been invented by another. The Office Action further rejects claims 1 to 12, 15 to 21, 24 to 26, 28, 29, 32 to 37, 40 to 45, 48 to 55, 57, 58 and 61 as anticipated by Scholarly Review ASIAO Journal article authored by Roberts et al. (“the *Roberts Article*”); claims 13, 14, 22, 23, 31, 38, 39, 46, 47, 56 and 60 as obvious over the *Roberts Article* in view of U.S. Patent No. 5,631,025 to Shockley et al. (“*Shockley*”); and claims 27, 30, 50 and 59 as obvious over the *Roberts Article* in view of U.S. Patent No. 6,409,699 to Ash (“*Ash*”).

A. PROVISIONAL DOUBLE PATENTING REJECTION

Applicant respectfully traverses the provisional rejection of claims 1, 5, 8, and 28 over co-pending U.S. patent application serial No. 10/624,150. In an effort to advance the prosecution of this application, independent claim 1 has been amended to

¹ It should be noted that the Office Action and original application indicated that claims 1 to 61 were filed and pending. The original claims were inadvertently misnumbered after claim 32, and indicated that the next claim was claim 29 (a duplicate) instead of claim 33.

recite, in relevant part, a cycler that pumps the dialysate into the fluid circuit and circulates the dialysate during a treatment period along the closed fluid path in a continuous manner to remove a therapeutically effective amount of solutes and ultrafiltrate from the patient. Dependent claims 5 and 8 have been similarly amended to depend from amended independent claims 1, and dependent claim 25 has been canceled. In light of these amendments, Applicants submits that the pending provisional double patenting rejections have been rendered moot and should be withdrawn.

B. CLAIM REJECTIONS UNDER 35 U.S.C. §102(f)

Applicant respectfully traverses the rejection of claims 1 to 65 under 35 U.S.C. 102(f) as not invented by Applicant in light of the disclosure of co-pending U.S. patent application serial No. 10/624,150. In particular, as discussed above in Section II-A, the claimed subject matter of the present application and the relied upon co-pending application are directed to distinct and different inventions. Moreover, Applicant submits that regardless of the alleged similarities between the specification, the single closed loop fluid path disclosed in the Abstract of the present application is clearly distinct from the multi-pass continuous flow dialysis therapy system disclosed in the Abstract of the relied upon co-pending U.S. patent application serial No. 10/624,150. For all of these reasons, Applicant submits that the disclosed and claims subject matter was invented by Applicant. Thus, the rejections under 35 U.S.C. §102(f) are unwarranted and improper and should be withdrawn.

C. CLAIM REJECTIONS UNDER 35 U.S.C. §102(b)

Applicant respectfully traverses the rejection of claims 1 to 12, 15 to 21, 24 to 26, 28, 29, 32 to 37, 40 to 45, 48 to 55, 57, 58 and 61 as anticipated² by the *Roberts Article*. In particular, the independent claims 1, 9, 18, 28, 32, 38, 45, 55 and 61 recite a system and method that includes, in relevant part, a fluid circuit in fluid communication with a catheter thereby defining a closed fluid path capable of circulating fluid into, through and out of the peritoneal cavity of a patient. In other words, system and method are closed to the atmosphere to prevent contamination.

² "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The *Roberts Article* does not disclose a closed system, in fact the system of *Roberts* is specifically discussed in the present application to highlight the limitations and disadvantages that the claimed invention was designed, in part, to overcome. Specifically, as discussed in the “Background of the Invention” section:

[0006] Another type of hemodialysis therapy is regenerative hemodialysis. This therapy uses a hemodialysis system, which includes a cartridge for dialysate regeneration. One such cartridge is manufactured under the name REDY™ by Sorb Technology, Oklahoma City, Okla. In this system, the dialysate fluid flow path must be properly cleaned before the hemodialysis machine can be used on another patient. Also, **the dialysate fluid flow path is not a closed system. In this regard, the dialysate fluid flow path is open to the atmosphere such that air borne pathogens can contact the fluid in the system and foster the growth of bacteria in same.** Consequently, contamination of such a dialysis system can be problematic. Thus, the dialysate fluid exiting the REDY™ cartridge is not suitable for peritoneal dialysis. [Emphasis added].

It is clear from this passage that the above-discussed REDY™ device is the same system discussed and illustrated at page 373 (and FIG. 3) of the *Roberts Article*. Thus, it is clear that the system disclosed in the *Roberts Article* is not a closed system as recited by the claims at issue. For this reason, Applicant submits that the anticipation rejections are unwarranted and improper and should be withdrawn.

D. CLAIM REJECTIONS UNDER 35 U.S.C. §103

Applicant respectfully traverses the rejections of claims 13, 14, 22, 23, 27, 30, 31, 38, 39, 46, 47, 50, 56, 59 and 60 as obvious³ over the *Roberts Article* in view of *Shockley* or *Ash*. In particular, none of the cited references, either alone or in combination, teaches or suggests a closed fluid path as necessary to establish a *prima facie* case of obviousness.

³ To establish a *prima facie* case of obviousness, three basic criteria must be met.:

- (a) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- (b) Second, there must be a reasonable expectation of success.
- (c) Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2143 - §2143.03 for decisions pertinent to each of these criteria.

As previously discussed in Section II-C, the *Roberts Article* does not disclose or even suggest a closed fluid path, loop or system. Instead, the dialysate fluid flow path of the REDY™ system disclosed in the *Roberts Article* is open to the atmosphere and contaminants.

Shockley and *Ash* fail to provide the teaching or suggestion lacking in the *Roberts Article*. Specifically, *Shockley* simply discloses the use of dextrose as a part of an insulate supply and the removal of microglobulin. *Shockley* is completely silent regarding the configuration of the dialysis system or the fluid path or loop. Similarly, *Ash* discloses a system for performing dialysate in which a column of sorbents or a sorbent-based dialysis system regenerates peritoneal fluid. As with *Shockley*, *Ash* is silent regarding the configuration of the dialysis system or the fluid path or loop. Because, the *Roberts Article*, *Shockley*, and *Ash* do not disclose, or even suggest, a closed fluid path, these references, either alone or in combination, do not provide a proper basis for establishing a *prima facie* case of obviousness. For these reasons, Applicant submits that the obviousness rejections are unwarranted and improper and should be withdrawn.

III. CONCLUSION

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicit reconsideration of same. If questions arise during the examination of this application, Applicant requests that the Examiner contact Applicant's representative at the information provided below.

Respectfully submitted,

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